JUL 2 3 2004

K040913

Section 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared

a. Bausch & Lomb
180 Via Verde Dr.
San Dimas, CA 91773
(909) 971-5104

b. Contact Person: David U, Thomas, M.S., R.A.C.
Manager, Global Regulatory Affairs

c. Date Summary Prepared: December 19, 2003

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: NGDI (Next Generation Diagnostic Instrument)

b. Classification Name: Ophthalmic Refractometer, AC Powered Keratascopy and AC Powered SlitLamp Biomicroscope

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Ortek, Inc
Device: Orbscan II
510(k) K984443
Date Cleared: March 5, 1999

Company: Bausch & Lomb, Incorporated
Device: Zywave Wavefront Diagnostic System

510(k)	K010992
Date Cleared:	Class I, Exempt
Company:	Bausch & Lomb, Incorporated
Device:	Documenting Laser Slit Lamp
510(k):	K012873
Date Cleared:	November 19, 2001

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The NGDI Workstation comprises two individual measuring systems.

The Anterior Segment Analyzer measures elevation and curvature on both the anterior and posterior surfaces of the cornea, full corneal pachymetry, white-to-white, anterior chamber depth and angle kappa.

The Anterior Segment Analyzer in the NGDI Workstation is a diagnostic system that provides a complete analysis of the eye's optical system by utilizing slit scanning technology with an advanced Placido disc system. The slit scan is used to create the pachymetry model in the NGDI Workstation, which gives the thickness of the cornea and the location of the lens.

The Aberrometer is a precision optical instrument which measures the deviation of light beams reflected off the eye's retina to define the wavefront deformation as a function of the position of the pupil. It uses a motor-controlled trombone to set up the optical path for the eye image to return through in complete focus.

The Aberrometer function of the NGDI employs the principles of Hartman-Schack wavefront sensing in which a narrow illumination beam from a 785 nm, low power, laser diode goes into the eye and focuses into a diffraction limited point on the retina. The light reflects off the retina and comes back out the eye. The light exiting the eye is then passed through an array of tiny lenses (the lenslet array) that tak the exiting rays of light and breaks them into small points. With a normal, regular pattern, one can see where there is a plain wavefront with a uniform and symmetric grid and regular spacing between the points. Aberrated wavefronts are characterized by a distortion of the grid pattern after the light passes through the lenslet array.

5. Statement of intended use:

Indicated use is for scanning, mapping, and displaying the geometry of the anterior segment of the eye. Also a diagnostic instrument indicated for the automated measurement and analysis of optical aberrations of the eye by use of wavefront technology.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Table A - Comparative Technological Characteristics

CHARACTERISTICS	Bausch & Lomb NGDI	ORBSCAN II	ZYWAVE
Indications for use	Indicated use is for scanning, mapping, and displaying the geometry of the anterior segment of the eye. Also a diagnostic instrument indicated for the automated measurement and analysis of optical aberrations of the eye by use of wavefront technology.	Indicated use is for scanning, mapping, and displaying the geometry of the anterior segment of the eye.	Automated measurement and analysis of optical aberrations of the eye by use of wavefront technology.
Operating principle	Hartmann-Schack	N/A	Same
Measurement range	Sphere -12 to +6 diopters Cylinder 0 to 6 diopters Axis 0-180 degrees		Sphere -8 to +6 diopters Cylinder 0 to -6 diopters Axis 0-180 degrees
Acquisition Head	Same except for light source (see below).	Scanning slit HiRes video CCD camera Fully coated optics Coaxially fixation light Optical Positioning Aid	
Light Source	Laser slit technology (red, 660 nanometer)	Incandescent Light source using mechanical aperture to generate slits.	
	Trombone Laser Injection 780 nanometers 1 millimeter off axis.		Direct Laser Injection 780 nanometers 1 millimeter off axis.

7. Brief summary of nonclinical tests and results:

Repeatability data was collected for a number of test objects. This was done for the NGDI and Orbscan. The comparisons were made in terms of average Keratometric Power (referred to as Diopters and abbreviated as D in this document), which is related to the Radius of Curvature by the formula

$$P_k = 337.5 / R_{c(mm)}$$

Presented in Table B are the Power results of the repeatability study for test objects.

Table B – Overall Repeatability of Keratometric Power (Test Objects)

	RMS Repeatability of Average Power, Diopters	
	Orbscan	NGDI
Root Mean Square Repeatability	0.04	0.05

Instrument repeatability represents only a portion of the total error. Systematic errors can occur for a variety of reasons, and as a result, the variances for absolute error are generally larger than the Root Mean Square repeatability. Because the curvatures of the test objects are known, the error statistics can be computed. The results are presented in Table C.

Table C – Error Statistics (Test Objects)

Statistic	**Error, Diopters**	
	Orbscan	NGDI
Mean	0.05	0.00
Standard Deviation	0.09	0.05
Root Mean Square	0.10	0.05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Bausch & Lomb
c/o Intertek Testing Services
Daniel W. Lehtonen, Staff Engineer
70 Codman Hill Rd.
Boxborough, MA 01779

Re: K040913
Trade/Device Name: NGDI (Next Generation Diagnostic Instrument)
Regulation Number: 21 CFR 886.1850
Regulation Name: Biomicroscopes
Regulatory Class: Class II
Product Code: MXK; HJO; NCF
Dated: July 9, 2004
Received: July 13, 2004

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040913

Indications for Use

510(k) Number (if known):

Device Name: NEXT GENERATION DIAGNOSTIC INSTRUMENT (NGDI)

Indications For Use:

Indicated Use is for scanning, mapping, and displaying the geometry of the anterior segment of the eye.

Also indicated for the measurement and analysis of optical aberrations of the eye by use of wavefront technology.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K040913